

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW YORK**

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SONIA BERMAN, individually and on
behalf of all others similarly situated,

Plaintiff,

-against-

DAVOL, INC. and C.R. BARD, INC.,

Defendants.

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**CLASS ACTION
COMPLAINT**

Index No. 08cv4869
Judge Richard J. Holwell
Magistrate Judge Henry
Pitman

Sonia Berman (“Plaintiff” or “Ms. Berman”), individually and on behalf of all others similarly situated, by and through her attorneys, the Law Offices of G. Oliver Koppell and Associates, as and for her complaint against the defendants Davol, Inc. (“Davol”) and C.R. Bard, Inc. (“Bard”)(collectively “Defendants”), alleges as follows:

NATURE OF THE ACTION

1. Plaintiff on behalf of herself and on behalf of the Class as defined in paragraph 24 below (the “Class”), brings this action against C.R. Bard, Inc. and its wholly owned subsidiary, Davol, Inc., for their sale and distribution of defective Composix Kugel Mesh Patches (“Kugel Patch”). The Defendants’ defective product was surgically implanted into the bodies of Plaintiff and the Class. The Kugel Patch presented a substantial risk of injury to Plaintiff and the Class and required removal. As a result, Plaintiff and the Class have been injured and will need continual and ongoing medical monitoring.

THE PARTIES

2. Plaintiff is a citizen and resident of the County of New York, State of New York.

3. Defendant, DAVOL INC. (“Davol”) is a corporation incorporated under the laws of the State of Rhode Island. Davol’s principal place of business is in the State of Rhode Island. It manufactures the Kugel Patches at 100 Sockanosset Crossroad, Cranston, Rhode Island 02920. Davol has a registered agent in Rhode Island at CT Corporation System, 10 Weybosset Street, Providence, Rhode Island. Davol focuses its business on products in key surgical specialties, including hernia repair, hemostasis, orthopedics, and laparoscopy. Upon information and belief, Davol does business in the State of New York.

4. Defendant, C.R. BARD, INC. (“Bard”) is a corporation incorporated under the laws of the State of New Jersey. Bard is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of the Kugel Patch. Upon information and belief, Bard dominates and controls Davol with respect to the design, manufacture and distribution of the Kugel Patch. Bard has a registered agent in New Jersey at Stephen J. Long, 730 Central Avenue, Murray Hill, New Jersey. Bard also manufactures and supplies Davol with material that forms part of the Kugel Patch. Bard at all relevant times did substantial and continuous business in the state of Rhode Island. Upon information and belief, Bard does business in the State of New York.

BASIS OF JURISDICTION AND VENUE

5. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332(d)(2) and (6) of the Class Action Fairness Act of 2005. Plaintiff and each member of the putative Class have suffered aggregate damages exceeding five million dollars

(\$5,000,000), exclusive of interests and costs.

6. The Court has personal jurisdiction over Defendants Davol and Bard because of its presence and activities in this judicial district.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §1391(a) because this is a civil action wherein jurisdiction is founded on diversity of citizenship and either or both of the following is true: a substantial part of the events or omissions giving rise to the claim occurred here, and/or Defendants are subject to personal jurisdiction here.

FACTS

8. The Kugel Patch is a medical device designed for use in patients undergoing hernia surgery. Kugel Patches were designed to treat central hernias caused by the thinning or stretching of scar tissue that forms after hernia surgery.

9. Defendant Davol designed, manufactured, and distributed the Kugel Patch, a hernia mesh patch that was implanted into the bodies of the Plaintiff and members of the Class.

10. Defendant Davol, through its agents, servants, and employees, participated in the manufacture and delivery of the Kugel Patches that were implanted into and inserted into the bodies of Plaintiff and the Class.

11. Defendants submitted their 510K Application to the Federal Drug Administration (hereinafter referred to as the “FDA”) on January 22, 2001. Following this 510K Application, the Kugel Patch was authorized by the FDA as a Class II medical device.

12. The Kugel Patch hernia repair products implanted in the bodies of Plaintiff and members of the Class were designed, manufactured, sold and distributed by Davol to be used by surgeons for hernia repair surgeries and was further represented by Davol to be an appropriate, cost-effective, and suitable product for such purpose.

13. An FDA Class I recall is issued for problems related to medical devices that are potentially life threatening or could cause a serious risk to health.

14. On December 22, 2005, Davol recalled many sizes of Kugel Patches under an FDA Class I recall notice.

15. The Kugel Patches were recalled due to a faulty “memory recoil ring” that can break under pressure. Incidents of ring migration, intestinal fistulae, bowel perforation, and even death have been reported.

16. Upon information and belief Davol and Bard failed to comply with the FDA application and reporting requirements.

17. Upon information and belief Davol and Bard were aware of the high degree of complication and the failure rate associated with their Kugel Patch before it was recalled.

18. Upon information and belief Davol and Bard were aware of the defect in manufacture and design of the Kugel Patch prior to the recall of their Kugel Patches.

PLAINTIFF’S EXPERIENCE

19. On September 22, 2005, Ms. Berman underwent surgery to repair a ventral hernia. A size 8 x 11.75cm Kugel Patch was used to repair the hernia. The operative report states that Ms. Berman had a herniation in the left lower quadrant which was

corrected by implanting the mesh patch. The patient was returned to the recovery room in a stable condition.

20. The Kugel Patch implanted into Ms. Berman was designed, manufactured, sold and distributed by Defendants, and was intended to be used by surgeons for hernia repair surgeries. Defendants represented these Kugel Patches to be appropriate and suitable products for such purposes.

21. After extreme abdominal discomfort, as well as a large, symptomatic bulge in Ms. Berman's lower left quadrant, Ms. Berman's physician advised her that the Kugel Patch needed to be removed because it posed a serious ongoing health risk due to its defective design and manufacture.

22. On October 15, 2007, Ms. Berman had the Kugel Patch removed through a surgical procedure. The operative report states that Ms. Berman had intercostal nerve injury due to the Kugel Patch.

23. As a direct and proximate result of Defendants' design, manufacture and inadequate warnings regarding the Kugel Mesh Patch, Ms. Berman has sustained and will continue to sustain injuries and damages and will require ongoing medical monitoring.

CLASS ACTION ALLEGATIONS

24. Plaintiff brings this class action on behalf of herself and on behalf of all others similarly situated, as members of a proposed nationwide plaintiff class defined as follows:

All citizens, residents or domiciliaries of the United States, who have had a Kugel Patch implanted into their person, but as a result of the defective design and function of the Kugel Patch, were required to have the device removed.

25. This action is brought and may be properly maintained as a class action pursuant to the provisions of Rule 23(a)(1)-(4), 23(b)(2), and 23(b)(3). This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of Rule 23.

26. The Class is so numerous that the individual joinder of all its members is impracticable. The exact number and identification of Class members is currently unknown and can only be ascertained through appropriate discovery of Defendants. Upon information and belief, there are thousands of members of the Class.

27. Common questions of fact and law exist as to all members of the Class which predominate over any questions affecting only individual members of the Class. These common questions include:

- Whether there are design and/or manufacturing defects in the Kugel Patch;
- Whether Defendants failed to follow FDA good manufacturing practices, failed to properly investigate adverse manifestations of the Kugel Patch over the past several years, failed to adequately document reports of the defect, and failed to exercise adequate quality control;
- Whether Defendants' conduct in designing, manufacturing, marketing and monitoring the Kugel Patch fell below the duty of care owed by Defendants to Plaintiff and the Class;
- Whether Defendants intentionally, knowingly, carelessly, recklessly or negligently concealed information regarding the existence of a defect in the Kugel Patch from the FDA, physicians, Plaintiff and the Class;

- Whether the Kugel Patches share a common and inherent design defect that causes them to break, creating a risk of injury or death to patients in whom they are implanted;
- Whether Defendants negligently, recklessly, or intentionally misrepresented the quality and usefulness of the Kugel Patch;
- Whether Defendants are liable for selling a dangerously defective product;
- Whether the Class has been injured by virtue of Defendants' deceptive business practices and conduct;
- Whether the class is entitled to equitable relief, and, if so, the nature of such relief; and
- Whether Defendants are liable for punitive or exemplary damages, and if so, the amount necessary and appropriate to punish Defendants for their conduct, to deter others, and to fulfill the other policies and purposes of punitive and exemplary damages.

28. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and the members of the Class have suffered similar injury and are facing further damages arising out of Defendants' common course of conduct. The economic losses of each Class member were caused directly by Defendants' conduct. Plaintiff and the members of the Class must prove the same facts in order to establish the same claims, which apply to all Class members.

29. Ms. Berman is an adequate representative of the Class because she has suffered due to the implantation of a Kugel Patch. She will continue to incur medical expenses related to the Kugel Patch. Plaintiff's interests do not conflict with the interests

of the Class members she seeks to represent. Plaintiff has retained experienced and competent counsel. Plaintiff and her counsel will fairly and adequately protect the interests of the Class members.

30. A class action is superior to other available methods for the fair and efficient adjudication of this litigation because individual litigation of the claims of the Class is impracticable. It would be unduly burdensome to the courts if thousands of individual cases were to proceed. Individual litigation presents a potential for inconsistent judgments which would establish incompatible standards of conduct for the Defendants, would create the risk of adjudication with respect to Class members which would be dispositive of the interests of other Class members, and which would create an inequitable allocation of recovery amongst those with equally meritorious cases.

AS AND FOR A FIRST CAUSE OF ACTION FOR NEGLIGENCE

31. Plaintiff and the Class repeat and re-allege each of the allegations contained in paragraphs 1-30 as though fully set forth herein.

32. Davol and Bard at all times mentioned had a duty to properly manufacture, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings and prepare for the Kugel Patch.

33. Davol and Bard at all times mentioned knew or in the exercise of reasonable care should have known, that the Kugel Patches were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with the proper warnings, and were unreasonably likely to injure the Kugel Patch's users.

34. Davol and Bard so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the Kugel Patch, that they were dangerous and unsafe for the use and purpose for which they were intended.

35. Defendants Davol and Bard knew or reasonably should have know that some Kugel Patches were at risk of failure and could cause injury and damage while they were engaged in the studying, testing, designing, developing, manufacturing, inspecting, producing, advertising, marketing, promoting, distributing, and or selling of the Kugel Patches for hernia repair surgery, specifically in that the “memory recoil ring” upon being subjected to stress after placement in the intra-abdominal space posed a significant risk of breakage, separation, migration, tearing, and splitting that posed the danger of severe harm and death to patients.

36. Davol and Bard were aware of the probable consequences of the defective Kugel Patches. Davol and Bard knew or should have known the Kugel Patch would cause serious injury; they failed to disclose the known or knowable risks associated with the Kugel Patch. Davol and Bard willfully and deliberately failed to avoid those consequences, and in doing so, Davol and Bard acted in conscious disregard of the safety of Ms. Berman and the Class.

37. Defendants Davol and Bard owed a duty to Plaintiff and the Class to adequately warn them and their treating physicians, of the risks of breakage, separation, tearing and splitting associated with the Kugel Patch and the resulting harm and risk it would cause patients.

38. Upon information and belief, Defendants Davol and Bard breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Kugel Patch.

39. As a direct and proximate result of the duties breached, the Kugel Patch used in Ms. Berman's hernia repair surgery was removed, resulting in Ms. Berman suffering pain and harm. Upon information and belief, all members of the Class had a similar experience.

40. As a result of the foregoing, Plaintiff and the Class she represents have suffered injuries and damages as a direct consequence of Defendants' negligence.

41. Davol's and Bard's conduct in continuing to market, sell and distribute the Kugel Patches after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others, justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Davol, Bard and others from similar conduct in the future.

**AS AND FOR A SECOND CAUSE OF ACTION FOR VIOLATION OF THE
NEW YORK DECEPTIVE ACTS AND PRACTICES LAW UNDER GENERAL
BUSINESS LAW §349 & THE SIMILAR LAWS OF THE FIFTY STATES**

42. Plaintiff and the Class repeat and re-allege each of the allegations contained in paragraphs 1-41 as though fully set forth herein.

43. Defendants Davol and Bard are merchants, who study, test, design, develop, manufacture, inspect, produce, market, promote, advertise, distribute, and/or sell the Kugel Patch for hernia repair surgery.

44. Defendants Davol and Bard knowingly committed unfair and deceptive practices in their study, test, design, development, manufacture, inspection, production marketing, promotion, advertising, distribution and/or sale of the Kugel Patch for hernia repair surgery.

45. Defendants Davol and Bard knowingly committed unfair and deceptive practices while they failed to safely design and construct an effective Kugel Patch for hernia repair surgery.

46. Davol and Bard deceptively did not inform the FDA prior to December 2005 of its knowledge concerning the dangers posed to patients of its Kugel Patches which were susceptible to failure and subject to the Class I recall.

47. Davol and Bard deceptively did not inform the public at large prior to December 2005 of its knowledge concerning the dangers posed to patients of its Kugel patches which were susceptible to failure and subject to the Class I recall.

48. Davol and Bard deceptively failed to give adequate warnings regarding the use and potential problems with such patches used for hernia repair.

49. Davol's and Bard's actions occurred while they were engaged in trade and commerce, and all of the conduct occurred during the course of their business.

50. As a result of the foregoing, Ms. Berman and the Class suffered injuries and damages as a direct consequence of Defendants' actions and inactions.

51. Davol's and Bard's conduct in continuing to deceptively market, sell and distribute the Kugel Patch after obtaining knowledge that they were failing and not performing as represented and intended, showed a complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for

aggravating circumstances in such a sum which will serve to deter Davol, Bard and others from similar conduct in the future.

**AS AND FOR A THIRD CAUSE OF ACTION FOR STRICT PRODUCT
LIABILITY**

52. Plaintiff and the Class repeat and re-allege each of the allegations contained in paragraphs 1-51 as though fully set forth herein.

53. Davol and Bard designed, manufactured, assembled, distributed, conveyed and/or sold the Kugel Patch for hernia repair surgery.

54. The Kugel Patches subject to the Class I recall were defective because they failed to perform safely and effectively for the purpose they were designed. Ms. Berman and the Classes Kugel Patches were recalled devices that required the subsequent painful and unnecessary surgical removal of their Kugel Patches.

55. At all times mentioned, the Kugel Patch was substantially in the same condition as when it left the possession of Davol.

56. The Kugel Patch implanted into Ms. Berman and the Class was being used in a manner reasonably anticipated at the time it was implanted in them by their surgeons and/or medical providers.

57. The Kugel Patches, like the one found in Ms. Berman, at the time they left the possession of Davol and Bard were inherently dangerous for their intended use and were unreasonably dangerous products which presented and constituted an unreasonable risk of danger and injury to Ms. Berman and members of the Class as follows:

- i. The Kugel Patch was sold in a defective condition by design and manufacture;

- ii. The Kugel Patch as designed and manufactured was unsafe to Ms. Berman and members of the Class;
- iii. The Kugel Patch as designed and manufactured was unreasonably dangerous to Ms. Berman and members of the Class;
- iv. The Kugel Patch did not perform safely as an ordinary consumer/patient, like Ms. Berman and the Class, would expect;
- v. The Kugel Patch as designed and manufactured was unsafe for its intended use;
- vi. Davol and Bard failed to warn the end user or their medical providers about the dangers and risks of the product;
- vii. Davol and Bard knew the component parts of the Kugel Patch as implemented through design and/or manufacture could cause injury to the end user;
- viii. Davol and Bard failed to design and manufacture an adequate, safe, and effective “memory recoil ring.” Its interaction with the mesh of the Kugel Patch did not withstand the foreseeable stresses it was subject to within the intra-abdominal space; and
- ix. Davol and Bard failed to avoid migration of the Kugel Patch and/or its components from the initial site of the hernia repair surgery.

58. As a result of the foregoing, Ms. Berman and the Class suffered injuries and damages as a direct consequence of Defendants' actions and inactions.

59. Davol's and Bard's conduct in continuing to market, sell and distribute the Kugel Patch after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Davol, Bard and others from similar conduct in the future.

**AS AND FOR A FOURTH CAUSE OF ACTION FOR NEGLIGENT
INFLICTION OF EMOTIONAL DISTRESS**

60. Berman and members of the Class repeat and re-allege each of the allegations contained in paragraphs 1-59 as though fully set forth herein.

61. Berman and members of the Class suffered severe emotional distress, which was as a result of Defendants' negligent conduct in studying, designing, developing, testing, inspecting, manufacturing, producing, advertising, marketing, promoting, distributing, and/or selling of the Kugel Patch for hernia repair surgery.

62. As a result of Davol's and Bard's negligent conduct in failing to adequately and safely design and construct an effective safe Kugel Patch for hernia repair surgery, Ms. Berman and members of the Class had to undergo additional surgeries to have the defective Kugel Patch removed. These additional surgeries, coupled with the fear of such surgeries, the recuperative period following such surgeries and the ongoing fear relating to having a defective device implanted in the body caused Plaintiff and all members of the class extreme emotional upset and distress. Therefore, Davol and Bard are liable to Ms. Berman and the Class.

63. As a result of the foregoing, Plaintiff and members of the Class suffered injuries and damages due to Defendants' negligence.

64. Davol's and Bard's conduct in continuing to market, sell and distribute the Kugel Patch after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Davol, Bard and others from similar conduct in the future.

AS AND FOR A FIFTH CAUSE OF ACTION FOR BREACH OF WARRANTY

65. Berman and the Class repeat and re-allege each of the allegations contained in paragraphs 1-64 as though fully set forth herein.

66. Davol and Bard sold the Kugel Patches that were implanted in Berman and members of the Class. Davol and Bard warranted to Berman and the Class, their physicians and health care providers, that the Kugel Patch was of merchantable quality and safe for the use for which they were intended.

67. Davol and Bard knew or should have known that the Kugel Patch at the time of sale was intended to be used for the purpose of surgically implanting them into the body for hernia repair.

68. Plaintiff, the Class, their physicians and health care providers reasonably relied on Davol's and Bard's judgment, indications, and statements that the Kugel Patch was fit for such use.

69. When the Kugel Patches were distributed into the stream of commerce and sold by Davol and Bard, they were unsafe for their intended use, and not of merchantable

quality, as warranted by Davol and Bard in that they had very dangerous propensities when used as intended and implanted into a patient's body where they could cause serious injury of harm or death to the end user.

70. Plaintiff and the Class suffered such injuries and damages as a result of Davol's and Bard's conduct and actions.

AS AND FOR A SIXTH CAUSE OF ACTION FOR FAILURE TO WARN

71. Plaintiff and the Class repeat and re-allege each of the allegations contained in paragraphs 1-70 as though fully set forth herein.

72. In the course of business, Davol and Bard designed, manufactured, and sold the Kugel Patch to Lenox Hill Hospital and numerous other health care providers and institutions for hernia repair surgeries.

73. At the time of the design, manufacture and sale of the Kugel Patch, they were defective and unreasonably dangerous when put to their intended and reasonably anticipated use. Bard and Davol knew or in the exercise of reasonable care should have known of the defective nature of the Kugel Patch and the danger posed by its use. Further, the Kugel Patches were not accompanied by proper warnings regarding significant adverse consequences associated with the Kugel Patch.

74. Bard and Davol failed to provide any warnings, labels or instructions calling attention to the Kugel Patches' dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the products involved significant dangers not readily obvious to the ordinary user of the products. Bard and Davol failed to warn of the known or knowable injuries associated with malfunction of the Kugel Patch, including but not limited to rupture of

the Patch and severe peritonitis and infection which would require subsequent surgical procedures and could result in severe injuries.

75. The dangerous and defective conditions in the Kugel Patches existed at the time they were delivered by the manufacturer to the distributor and/or health care providers. At the time Plaintiff and the Class had their hernia repair surgeries, the Kugel Patch was in the same condition as when manufactured, distributed, and sold.

76. Berman and the Class's hospitals and surgeons did not know at the time of use of the Kugel Patch, or at any time prior thereto, of the existence of the defects in the Patches.

77. As a result of the foregoing, Berman and the members of the Class suffered the aforementioned injuries and damages as a direct result of Davol and Bard's failure to warn.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff and the Class respectfully request judgment in their favor as well as the following relief:

- a) Certifying the Class pursuant to Rules 23(a), 23(b2) and 23(b3) of the Federal Rules of Civil Procedure, certifying Plaintiff as representative of the Class and designating her counsel as counsel for the Class;
- b) Declaring that Defendants have engaged in the unlawful and inequitable conduct alleged herein;
- c) Awarding Plaintiff and the Class:
 - i) Compensatory damages;
 - ii) Statutory damages;

- iii) Punitive damages;
- iv) Plaintiff's costs of this action, together with her reasonable attorneys' fees to the full extent permitted by law;
- v) Interest on all amounts due;
- vi) Granting injunctive relief ordering Defendants to provide Plaintiff and the Class ongoing medical monitoring; and
- vii) Such other and further relief as this court deems just and proper.

JURY DEMAND

Plaintiff and the Class demand a trial by jury on all issues except for those issues for which injunctive relief is requested.

Dated: New York, New York
May 23, 2008

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